

REMARKS

All the claims submitted for examination in this application have been made subject to a restriction requirement imposed under 35 U.S.C. §§121 and 372.

The Official Action avers that four distinct and independent inventions are embodied in the claims of the present application. These inventions are defined as Groups I to IV.

Group I encompasses Claims 1-8, 10-7, 22, 36, 42 and 43 in part, drawn to pyridine compounds and pharmaceutical uses of those compounds. The “in part” limitation on the aforementioned claims is based on the requirement that A in Formula I is nitrogen.

The second invention, Group II, encompasses all of the claims in Group I in part wherein A in Formula I is carbon. That is, the second invention is directed to Claims 1-8, 10-17, 22, 36, 42 and 43, drawn to phenyl compounds and pharmaceutical uses thereof. In addition, the invention of Group II also encompasses Claims 9, 18 to 21, 23-27 and 32-35.

The third invention, denoted as Group III, includes Claims 28-31 in part, drawn to a method of imaging amyloid deposits. Again, this invention is recited to represent the claims only in part insofar as it applies only to embodiments where A in Formula I is nitrogen.

The fourth and last invention, denoted as Group IV, is also directed to Claims 28-31 in part, drawn to a method of imaging amyloid deposits, where A in Formula I is carbon.

The predicate for the imposition of the instant restriction requirement is based on the allegation that the claims of Groups I to IV do not relate to a single general inventive concept as required under PCT Rule 13.1. This is so because, contrary to PCT Rule 13.2, all the claims lack the same or corresponding special technical features. Specifically, the special technical feature of Group I is a compound containing a pyridine ring, a 6-membered ring

with a heterocyclic nitrogen atom. On the other hand, the claims of Group II allegedly possess a different special technical feature, a compound containing a phenyl ring.

The special technical feature of the claims of Groups III and IV the Official Action argues, different from the special feature of Groups I and II, is that they are drawn to a method of imaging using labeled compounds. The compounds of Groups III and IV are labeled, whereas the compounds of Groups I and II are not. Moreover, the use of the compound, imaging, in the claims of Groups III and IV is different from the pharmaceutical use of the claims of Groups I and II. As between Groups III and IV, the special technical features of each are different from each other based on the use of a pyridine and phenyl ring, respectively, as discussed above.

As stated above, applicants have elected the claims of Group II for prosecution on the merits in this application. This election is made with traverse.

Although applicants concede that 37 C.F.R. §372(b)(2) permits the USPTO to consider the question of unity of invention within the scope of the requirements of the PCT, it is noted that the corresponding PCT application was the subject of an International Preliminary Examination Report, prepared under PCT Article 36 and Rule 70. That Report did not identify any lack of unity of invention amongst similar claims. In view of the fact that the International Preliminary Examination Report was prepared by an examiner expert in the intricacies of the Patent Cooperation Treaty, applicants believe that the judgment made in that initial examination is determinative of unity of invention of all 43 claims in the present application.

This position is particularly appropriate given the flaws in the analysis predicated the restriction requirement of record. The basis for restriction between Groups I and II is the

alleged distinction between compounds of Formula I wherein the meaning for A is nitrogen or CH. That is, in the former case, a pyridine group is included in the compounds utilized in the method of the present invention whereas in the latter case a phenyl group is included in the compounds employed in the identical method.

Applicants submit that this distinction does not support a restriction requirement. Obviously, this predicate for imposition of a restriction requirement is inadequate under USPTO regulations. That is, there is no section of the Manual of Patent Examining Procedure that permits the imposition of a restriction requirement based on different meanings of a radical within a single generic chemical formula.

The principle attempted to be promulgated in the present application, taken to its logical conclusion, eliminates prosecution of applications which are directed to generic formulae insofar as any radical therein having more than one meaning can be said to represent different technical features.

The theory of the present restriction requirement, if taken to its logical conclusion, permits unlimited restrictions between inventions where the other radicals are similarly restricted. This can lead to restriction of the claims of the present application to literally hundreds of inventions. Stated differently, the principle behind the instant restriction requirement will be the death knell to claims reciting generic formulae.

The error in the present restriction requirement, applicants respectfully urge, resides in the definition of a technical feature. Applicants respectfully submit that defining a technical feature so that species within a claimed genus, especially in a case where the claim is directed to a method of utilizing a class of compounds, is misplaced. That the PCT examining authority found no lack of unity of invention only confirms the aforementioned conclusion.

Reconsideration and removal of the restriction requirement, predicated upon the differences in the meaning of A in Formula I, is therefore deemed appropriate. Such action is respectfully urged.

The same analysis applies to the restriction between the claims of Groups III and IV. Applicants respectfully urge that no special technical features distinguish Claims 29 to 31 when the method of imaging amyloid deposits utilizes a compound where A is nitrogen or CH.

As far as the distinction between Claims 1 to 27 and 32-43, on the one hand, and Claims 28-31, on the other, applicants submit that the two methods are intertwined such that they do not represent distinct and independent inventions. That the compound of Formula I has a beneficial effect on treating Alzheimer's disease is predicted upon the ability of that compound to inhibit aggregation of amyloid proteins, also permits their imaging. As such, these two sets of claims are one invention and are not subject to restriction.

That is, it is apparent that the compound of Formula I acts on aggregated amyloid proteins. As such, that compound attaches to the aggregated amyloid proteins and thus permit their imaging when the compound is labeled. Applicants thus conclude that there is no patentable distinction between Claims 28-31 and the remaining claims of the present application.

Turning to the species election, applicants have elected the species 2-(4-(2-(3,4-dichlorophenyl)ethyl)phenyl)amino-benzoic acid for prosecution on the merits in the event that no generic claim is identified in the prosecution of this application. Applicants submit that Claims 1-3, 6-12, 15-18, 28-32, 42 and 43 read on this species.

Applicants have made the aforementioned species election with traverse. Applicants submit that it is well established that a reasonable number of species within the scope of a claimed genus may be examined in one application. So it is in the present application. The number of species within the scope of the generic Formula I is not so burdensome as to require applicants to limit the scope of the present application to that species. Applicants therefore request that the species election be rescinded.

The above remarks establish that the restriction requirement and species election of record are improperly asserted. Reconsideration and removal of the restriction requirement and the species election, followed by prompt examination on the merits of all the claims currently in this application, Claims 1-43, is therefore respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marvin Bressler", with a long, sweeping horizontal line extending to the right.

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